MEDI-CAL
CONTRACTING PROCEDURES
FOR
INCONTINENCE SUPPLIES

MEDI-CAL CONTRACTING PROCEDURES

FOR INCONTINENCE SUPPLIES

The Medi-Cal Medical Supply/Enteral Nutrition Benefit Branch of the Department of Health Care Services (Department) is responsible for reviewing and evaluating incontinence supplies for addition to, deletion from, or retention on the *Medi-Cal List of Incontinence Supplies* (List). The incontinence supplies subject to review are those that would be dispensed to fee-for-service Medi-Cal recipients and billed by pharmacy or durable medical equipment (DME) providers.

Incontinence supplies may be reviewed and evaluated *either* as part of a Product Category Review (PCR), *or* an Individual Petition. The Department will not begin a review unless the product has received appropriate marketing approval and the product is available on the market. The review and cost negotiations may result in a contract with the Department for product placement on the List. **This is NOT a competitive bid process.** Contracts are for Maximum Acquisition Cost (MAC) which is a guarantee by the contractor that any Medi-Cal provider can purchase the product at or below the contracted price. The contract negotiation process may result in multiple contractors' products appearing on the List. **A contract template for review purposes only may be requested from the project manager at any time during the review process**.

Confidentiality requirements are applicable to the Product Category Review and the Individual Petition process described in this document. Confidentially is required of all participants engaged in the contracting process. All anti-trust and collusion laws must be strictly adhered to by all.

Potential contractors may discuss products that have been proposed or petitioned to the Department, **but shall not reveal that products have been or will be added to the List**. Active promotions inferring that products have been or will be added to the List or discussions about pricing (offers or counter offers) shall not occur until the Provider Bulletins are published. Prices proposed to the Department, counter offers from the Department, and final contracted prices shall not be shared or announced until the Provider Bulletins are published. Failure to comply with confidentiality requirements may result in delay of the addition of products to the List, or cancellation of a signed contract.

At the conclusion of contract negotiations, but prior to the Provider Bulletin publishing dates, statute requires the Department to meet with representatives from the California Association of Medical Product Suppliers (CAMPS) and the California Pharmacists Association (CPhA). During this meeting the Department will share proposed or petitioned products and broad-spectrum product pricing with stakeholders, but will not disclose which specific products will be added to the List.

Product Category Review (PCR)

The Product Category Review, initiated by the Department, is a process by which products within a certain incontinence supply category are evaluated (see Product Review Process) based on the following criteria:

1. The safety of the product
2. The effectiveness of the product
3. The essential need for the product
4. The potential for misuse of the product
5. The immediate or long-term cost effectiveness of the product

The Department sends a notification letter to potential contractors inviting them to participate in the review process. Interested contractors are encouraged to keep the Department updated with a contact name, address, e-mail address, and phone number to ensure notification of an upcoming PCR. The notification letter will provide the contact information for the project manager assigned to the PCR. The PCR may result in contracts between the Department and one or more contractors.

Individual Petition

To accommodate **new** incontinence supply technology, new UPN/UPC numbers, or any changes to currently contracted products, an Individual Petition shall be submitted. Each product proposed in the Individual Petition is reviewed and evaluated (see Product Review Process) based on the following criteria:

1. The safety of the product.
2. The effectiveness of the product.
3. The essential need for the product.
4. The potential for misuse of the product.
5. The immediate or long-term cost effectiveness of the product

To submit an Individual Petition, the potential contractor must mail a letter on company letterhead listing all products proposed for addition to the List and/or an explanation of all changes made to currently contracted products, as applicable. The Individual Petition letter must be mailed to:

California Department of Health Care Services
Chief of Medical Supply/Enteral Nutrition Benefit Branch
PO Box 997417, MS 4604
Sacramento, CA 95899-7414

The project manager assigned to the Individual Petition will notify the potential contractor that the review has been initiated. Individual Petitions may be deferred to a PCR if such a review is currently scheduled or planned.

PRODUCT REVIEW PROCESS

Product Presentations

The project manager will offer potential contractors an opportunity to meet individually with the Department to discuss the review criteria; product studies and the contractor's business proposal (see sections below). Typically, a meeting room is scheduled for one and one-half hours for presentations. To allow time for questions and brief discussions, a presentation of no longer than one hour is recommended. Potential contractors should notify the project manager of the individuals attending the presentation. They may include product managers, sales managers and medical experts. Presenters must provide their own audio-visual equipment.

If a meeting with the Department is not desired, a document that addresses the review criteria, product studies, testing results (if applicable), and the business proposal must be submitted by mail.

Review Criteria

The Department shall, when evaluating incontinence supplies for addition to, deletion from, retention on, the *Medi-Cal List of Incontinence Supplies* (List), consider all of the following criteria:

(1) *Safety* - the relative freedom from side effects as determined by reviewing the contraindications, precautions, warnings, and adverse effects of the incontinence supply.

Evaluation of safety may involve a single incontinence supply or comparisons between two or more incontinence supplies, and may take into account such factors as safety of alternative methods of treatment.

(2) *Efficacy* - the speed, duration, and extent to which a incontinence supply will alleviate or control the medical condition of incontinence. Evaluation of efficacy may involve a single incontinence l supply or comparisons between two or more incontinence supplies, and may take into account such factors as efficacy of alternative methods of treatment.

(3) *Essential Need* - the incidence, severity and prognosis of the medical conditions for which an incontinence supply is indicated. Evaluation of essential need may involve a single incontinence supply or comparisons between two or more incontinence supplies, and may take into account such factors as the availability of alternative methods of treatment, whether an incontinence supply is curative agent or palliative in effect, or whether an incontinence supply may provide treatment for a medical condition not adequately treated by any other incontinence supply.

(4) *Misuse Potential* - the opportunity for unjustified, inappropriate, irresponsible, or improper use of an incontinence supply. Evaluation of misuse potential may take into account such factors as: utilization of incontinence supplies where there is insufficient medical necessity for its use; continued use of an incontinence supply despite loss of effectiveness; and/or utilization of an incontinence supply where a less costly but equally safe and efficacious alternative may be used.

(5) *Cost Effectiveness* - the immediate or long-term cost effectiveness of the product. Evaluation of cost will be based on the **NET COST** of the product to the Department. The net cost would include any statutory mark-up or dispensing fee.

As part of the cost evaluation, the Department considers data presented by the potential contractor related to the comparison of two or more treatment alternatives having identical outcomes (Cost-Minimization Analysis), the comparison of treatment alternatives which have different cost and treatment outcomes associated with them (Cost-Benefit Analysis), or the comparison of total health care system cost of treatment alternatives having similar treatment outcomes (Cost-Effectiveness Analysis).

Business Proposal

The potential contractor may submit one or more products for review. The following should be provided for each product proposed, both as hard copy and by email, on an Excel spreadsheet:

- Name or exact description of product
- Universal Product Number (UPN) for all package sizes
- HCPCS
- Catalog item number
- Size (if applicable)
- Price proposal
- Testing results (if applicable)

Product Evaluation

The Department will conduct an internal meeting to evaluate the product and/or product category following the presentations and receipt of business proposals. The project manager may request additional information from potential contractors.

The following information will be considered:

- Brief documentation of each of the five review criteria of safety, efficacy, essential need, misuse potential and cost effectiveness.
- Recommendations of other entities contacted for input and unsolicited input if appropriate.
- Manufacturer's product presentation
- Pertinent medical literature or other information
- Analysis of testing results (if applicable)

In the evaluation of the effectiveness of a product, the Department may require the potential contractor to submit its products to testing by an independent laboratory. For the purposes of this section, "independent laboratory" means an analytical laboratory that is not a subsidiary of, affiliated with, or on retainer for, the potential contractor.

Negotiations

The Department may present a price counter offer to the potential contractor following the product evaluation. The potential contractor may accept, reject, or present an alternative to the counter offer within the time frame requested by the project manager.

Decision Notification

Upon successful negotiations to add or retain a potential contractor's product on the List, the Department will send a contract to the potential contractor. Once the Department receives the contract signed by the potential contractor's representative, the Department will instruct its fiscal intermediary to inform providers of changes to the List (publish Medi-Cal provider bulletins) and to take action for processing provider claims for these incontinence supplies.

The project manager will notify the potential contractor of the proposed effective date the product will be added to the List. The effective date to add an incontinence supply is not official until the Medi-Cal provider bulletins are published. Potential contractors must not announce an effective date prior to the Medi-Cal bulletin publications.

If the Department decides not to contract for a product, notification regarding such a decision will be sent to the potential contractor.

Appeals

Potential contractors may appeal a negative decision by sending notice to the project manager within 30 calendar days of receipt of the Department's decision notification.

Additional Information

The *Medi-Cal List of Incontinence Supplies* and the *Medi-Cal List of Medical Supplies* are published in Part 2 of the *Medi-Cal Pharmacy Provider Manual* and Part 2 of the *Medi-Cal Allied Health Provider Manual*.

To learn more about the Medi-Cal Program and to view the *Medi-Cal List of Incontinence Supplies* and the *Medi-Cal List of Medical Supplies,* please visit the Medi-Cal website at: www.medi-cal.ca.gov .